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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,339	03/30/2006	Gap-Man Lim	F-9041	8943
28107 7590 03/23/2007 JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168			EXAMINER PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/574,339

Applicant(s)

LIM, GAP-MAN

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/06 & 8/06</u> | 6) <input type="checkbox"/> Other: ____ |

Claims 1-6 are pending in this application.

At the outset, it is suggested that applicant thoroughly review the specification to correct for grammar, syntax, etc. The following portion of the specification is illustrative of non-standard English usage throughout the specification (emphases added) (specification page 2):

tetrodotoxin among the toxicity of a swellfish is diluted and then the diluted tetrodotoxin has been used as an anodyne for a neuralgia, an arthritis, and a rheumatism patient, and it is known as to have sedation effect on a shock, an asthma, and a convulsions of tetanus and the like.

See also specification page 5 (emphases added):

The above powder of a starfish is also prepared the starfish containing a tetrotoxin. A starfish is allowed to dry at a temperature of 0°C ~ 30°C during from

Applicant is requested also to update the application data by inserting before the first line of the specification the fact that this application is a 371 of PCT/KR04/02680, filed on 10/19/2004.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) In independent method claim 1, there are too many “the above step” recitations. There should be more clarity as to which step the reference is directed.

(2) “the mixture formed by the above step” in claim 1, line 7 is confusing because there are many different mixtures that have been formed in steps above to line 7.

(3) It is unclear what the exact metes and bounds of “spawn” are. Is it limited to eggs of swellfish, or does it include developed larvae and less than fully mature adults?

(4) “mixing at heating state” in claim 1, line 7 should be rephrased. It is confusing phraseology.

(5) “firing the alcohol in the vessel by indirect transmission of heat” is confusing language in claim 1, line 9. The Examiner cannot understand what this means. Relatedly, in claim 5, “fired state by ignition of alcohol by indirect transmission of heat” is similarly confusing.

(6) Similarly, “remixing at the fired state” is also confusing in claim 1, lines 9-10. See also claim 5, lines 4-5.

(7) “cooling the mixture to a normal temperature” (emphasis added) in claim 1, lines 10-11, is confusing in view of claim 2. Since “heat-treatment” (emphasis added) can occur at 0°C, i.e. the freezing temperature of water, it is unclear what “normal”

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means in the context of a cooling temperature. Additionally, what is "normal" depends on the technology, material, circumstances. It is for applicant to define the cooling temperature, not for one skilled in the art to attempt to figure out what would be "normal" for such an unusual invention.

(8) It is unclear in claim 3 whether mixing ratio numbers for the weights of swellfish spawn and starfish are intended for the powder form or pre-powder form.

(9) Claim 4 is confusing because "said step forming a mixture" is indefinite. There are many steps for forming a mixture in the base claim.

(10) In claim 5, "The remedy ointment" should be amended to --- A remedy ointment ---.

(11) "above vessel" in claim 5 is improper language for referencing a previously mentioned vessel. Same comments apply to "above mixture" in claim 6.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a remedy ointment for piles and method for manufacturing the same. The nature of the invention is such that it utilizes an ingredient that is known to contain neurotoxins, spawn of a swellfish. **HCAPLUS abstract 1969:459095** discloses that eggs of puffer fish (swellfish) contain tetrodotoxin, which is extremely toxic. **Medline abstract 2000244099** discloses one death and two acute respiratory failures in one family that ingested puffer fish eggs. Dependent claims 4 and 6 further recite including *Charonia sauliae*, in powder form or otherwise. **Lee et al.** disclose that tetrodotoxin is a strong neurotoxin and it is found in *Charonia sauliae* (page 1698, left column). Applicant discloses in the specification that the invention encompasses using starfish that contains tetrodotoxin (page 5, lines 8-9). **Goldfrank et al.** disclose that mortality from tetrodotoxin poisoning approached 50% in one report (page 1089, right column). Various harmful effects are also disclosed (*id.*). Applicant admits in the specification that 0.5 mg of tetrodotoxin will kill a 50 kg human adult "on the spot" (page 1, lines 23-24).

The claims are extremely broad. With the exception of claim 3, no other claim specifies the content of the neurotoxin-containing spawn of a swellfish or starfish. Moreover, no claim specifies the content of the neurotoxin-containing *Charonia sauliae*. Apparently, the claims encompass maximized content of tetrodotoxin (see specification page 6, lines 10-11).

The state of the prior art, as discussed above, shows the dangers of using spawn of a swellfish or a *Charonia sauliae* because they contain neurotoxins that have dangerous and harmful effects on humans.

The level of one of ordinary skill in the art is extremely high given the use of a neurotoxin for medicinal purposes.

The level of unpredictability in the art is also extremely high because it cannot be predicted how adding starfish, banana, salt, water, alcohol, optionally *Charonia sauliae*, heating and cooling will affect the neurotoxins in the spawn of swellfish and *Charonia sauliae*. Applicant admits in the specification that tetrodotoxin is extremely stable to heat and acidity (page 1, lines 19-21).

The amount of direction provided by the inventor in the specification is very similar to the language set forth in the instant claims. In one sense, however, the direction provided by the specification actually makes the level of unpredictability even higher since maximizing the content of tetrodotoxin is taught (page 6, lines 10-11). There is not one working example in which a specific formulation with specific steps, quantities and proportions are made and subsequently applied as a "remedy ointment."

One skilled in the art is thus faced with the task of manufacturing a "remedy ointment for piles" by using as ingredients at least one and at most three substances that contain neurotoxins. There is no dispute that the neurotoxin that could be contained in swellfish, starfish and *Charonia sauliae* can be very dangerous to humans.

However, the instant specification provides guidance for maximizing tetrodotoxins. Even if the claims read on something less than purposefully maximizing tetrodotoxin content, its presence cannot be avoided in the current language of the claims. There is nothing in the state of the art that would suggest that a tetrodotoxin would not harm a patient with piles, and to the contrary, would "remedy" piles in ointment form. Thus, one skilled in the art would be faced with a quantity of experimentation that would be truly extraordinary. Virtually infinite variations of proportions of at least 5 ingredients (not counting hundreds of different species of marine organisms), temperatures, and duration of various process steps would have to be tried out and then each resultant product would have to be tested to determine whether piles could be remedied, as recited by the claim language.

Weighing all of the above noted factual considerations, the Examiner finds that one skilled in the art would need to resort to undue experimentation to make and use "a remedy ointment for piles," as claimed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'John Pak', is positioned above the printed name.

John Pak
Primary Examiner
Technology Center 1600